

ALVERSON TAYLOR & SANDERS
LAWYERS
6605 GRAND MONTECITO PKWY STE 200
LAS VEGAS, NV 89149
(702) 384-7000

ALVERSON TAYLOR & SANDERS
LEANN SANDERS, ESQ.
Nevada Bar No. 000390
JOEL BROWNING, ESQ.
Nevada Bar No.: 014489
6605 Grand Montecito Parkway, Ste. 200
Las Vegas, NV 89149
Telephone: (702) 384-7000
efile@alversontaylor.com

Thomas N. Sterchi (*Pro Hac Vice* motion to be filed)
Paul S. Penticuff (*Pro Hac Vice* motion to be filed)
BAKER STERCHI COWDEN & RICE, L.L.C.
2400 Pershing Road, Suite 500
Kansas City, MO 64108
Telephone: (816) 471-2121
sterchi@bscr-law.com
penticuff@bscr-law.com

Attorneys for Defendant
BRACCO DIAGNOSTICS, INC.

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

INGEBORG KLEIN and KARIN KLEIN,

Plaintiffs,

vs.

BAYER HEALTHCARE PHARMACEUTICALS
INC.; BAYER CORPORATION; BAYER
HEALTHCARE LLC, BRACCO DIAGNOSTICS,
INC.; GUERBET LLC; MALLINKRODT INC.;
MALLINKRODT LLC; and LIEBEL-FLARSHEIM
COMPANY LLC,

Defendants.

Case No.: 2:18-cv-01424-GMN-VCF

**TRIAL BY JURY IS HEREBY
DEMANDED**

**DEFENDANT, BRACCO DIAGNOSTIC, INC.'S
ANSWER TO PLAINTIFFS' COMPLAINT**

COMES NOW Defendant, Bracco Diagnostics Inc. ("BDI"), and answers and responds
to Plaintiffs' Complaint as follows:

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ANSWER TO SECTION ENTITLED
"PARTIES AND BACKGROUND"

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1. BDI admits that gadolinium is a heavy metal, rare earth element that may or may not be toxic depending on the circumstances. BDI denies the remaining allegations contained in Paragraph 1 of the Complaint.

2. BDI is without sufficient information to form a belief as to the truth of allegations in Paragraph 2 of the Complaint regarding the identity, residence, or alleged medical history of Plaintiffs, and therefore must deny the same. BDI denies that MultiHance® was administered to Plaintiffs. BDI denies the remaining allegations in Paragraph 2 of the Complaint.

3. BDI admits that gadolinium is a heavy metal, rare earth element that may or may not be toxic depending on the circumstances. BDI further states that, on December 19, 2017, the FDA again reiterated that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function, and we have concluded that the benefit of all approved GBCAs continues to outweigh any potential risks." To the extent that Paragraph 3 of the Complaint calls for medical or scientific conclusions prior to discovery, any such response by BDI would be premature at this time, and BDI therefore denies the remaining allegations contained in Paragraph 3 of the Complaint.

4. BDI denies the allegations in Paragraph 4 of the Complaint. BDI further states that MultiHance® is an FDA-approved contrast agent dispensed by prescription and that the language of its product labeling and package inserts has been approved by the FDA. BDI further states that, on December 19, 2017, the FDA again reiterated that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function, and we have concluded that the benefit of all approved GBCAs continues to outweigh any potential risks."

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1 5. BDI is without sufficient information and belief to form a belief as to the truth of
2 the allegations in Paragraph 5 of the Complaint, and therefore denies the same.

3 6. BDI is without sufficient information and belief to form a belief as to the truth of
4 the allegations in Paragraph 6 of the Complaint, and therefore denies the same.

5 7. BDI is without sufficient information and belief to form a belief as to the truth of
6 the allegations in Paragraph 7 of the Complaint, and therefore denies the same.

7 8. BDI is without sufficient information and belief to form a belief as to the truth of
8 the allegations in Paragraph 8 of the Complaint, and therefore denies the same.

9 9. BDI admits that it markets and sells MultiHance®, an FDA-approved contrast
10 agent dispensed by prescription, but denies the remaining allegations in Paragraph 9 of the
11 Complaint.

12 10. BDI admits that it is a Delaware corporation with its principal place of business
13 in New Jersey, and further admits that it is authorized to conduct business in Nevada. BDI
14 admits that it markets and sells MultiHance®, an FDA-approved contrast agent dispensed by
15 prescription, in the United States, and that MultiHance® is approved by the FDA for such
16 marketing and sale. BDI denies the remaining allegations in Paragraph 10 of the Complaint.

17 11. BDI is without sufficient information and belief to form a belief as to the truth of
18 the allegations in Paragraph 11 of the Complaint, and therefore denies the same.

19 12. BDI is without sufficient information and belief to form a belief as to the truth of
20 the allegations in Paragraph 12 of the Complaint, and therefore denies the same.

21 13. BDI is without sufficient information and belief to form a belief as to the truth of
22 the allegations in Paragraph 13 of the Complaint, and therefore denies the same.

23 14. BDI is without sufficient information and belief to form a belief as to the truth of
24 the allegations in Paragraph 14 of the Complaint, and therefore denies the same.

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15. BDI is without sufficient information and belief to form a belief as to the truth of the allegations in Paragraph 15 of the Complaint, and therefore denies the same.

16. The allegations contained in Paragraph 16 of the Complaint do not set forth any factual allegations, and therefore require no response from BDI. BDI states that, to the extent that allegations in the Complaint are addressed jointly to all defendants without distinction between them, BDI is not a corporate affiliate of unrelated defendants and has no knowledge – actual, constructive, or otherwise – as to actions, conduct, business practices, or behavior of those defendants. Accordingly, BDI responds solely on its own behalf, and denies knowledge or information as to the truth or falsity of any and all allegations as to the other remaining defendants, unless expressly averred otherwise.

**ANSWER TO SECTION ENTITLED
“JURISDICTION AND VENUE”**

17. BDI admits that subject matter jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332. BDI denies the remaining allegations in Paragraph 17 of the Complaint.

18. BDI denies that Plaintiffs have sufficiently pleaded the requisite minimum contacts of BDI with the State of Nevada that would support this Court’s or any other Nevada court’s exercise of personal jurisdiction over BDI, in that Plaintiffs have failed to sufficiently plead that Plaintiffs were administered MultiHance® within the State of Nevada. BDI is without sufficient information to form a belief as to the truth of the allegations in Paragraph 18 of the Complaint regarding other defendants, and therefore must deny the same. BDI denies the remaining allegations in Paragraph 18 of the Complaint.

19. BDI denies that Plaintiffs have sufficiently pleaded the propriety of venue in this district.

**ANSWER TO SECTION ENTITLED
“FACTS COMMON TO ALL CAUSES OF ACTION”**

20. BDI is without sufficient information to form a belief as to the truth, meaning or

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1 intent of the allegations in Paragraph 20 of the Complaint regarding Plaintiffs' alleged kidney
2 function, and therefore denies the same. BDI denies that Plaintiff Ingeborg Klein was
3 administered MultiHance®. BDI further states that, on December 19, 2017, the FDA again
4 reiterated that "[g]adolinium retention has not been directly linked to adverse health effects in
5 patients with normal kidney function, and we have concluded that the benefit of all approved
6 GBCAs continues to outweigh any potential risks." BDI denies the remaining allegations in
7 Paragraph 20 of the Complaint.
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9 21. BDI is without sufficient information to form a belief as to the truth, meaning or
10 intent of the allegations in Paragraph 21 of the Complaint regarding Plaintiffs' alleged medical
11 history, and therefore denies the same. BDI denies that gadolinium retention, if any, has been
12 found to cause adverse health effects in patients with normal kidney function, as the FDA again
13 reiterated on December 19, 2017. To the extent that Paragraph 21 of the Complaint calls for
14 medical or scientific conclusions prior to discovery, any such response by BDI would be
15 premature at this time, and BDI therefore denies such allegations. BDI denies the remaining
16 allegations in Paragraph 21 of the Complaint.
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18 22. BDI denies that gadolinium retention, if any, has been found to cause adverse
19 health effects in patients with normal kidney function, as the FDA again reiterated on
20 December 19, 2017. BDI further states that Paragraph 22 of the Complaint calls for medical or
21 scientific conclusions prior to discovery, such that any response by BDI would be premature at
22 this time, and BDI therefore denies the allegations in Paragraph 22. BDI denies the remaining
23 allegations contained in Paragraph 22 of the Complaint.
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25 23. BDI denies the allegations in Paragraph 23 of the Complaint, and further states
26 that MultiHance® is an FDA-approved contrast agent dispensed by prescription and
27 accompanied by FDA-approved labeling and package inserts, and that any and all
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1 contraindications, warnings, precautions, adverse reactions, and/or other information in the
2 MultiHance® labeling and package inserts were approved by the FDA and transmitted to
3 prescribing physicians and/or healthcare providers.

4 24. BDI denies the allegations in Paragraph 24 of the Complaint.

5 25. BDI denies the allegations in Paragraph 25 of the Complaint.

6 26. In response to Paragraph 26 of the Complaint, BDI admits that MultiHance® is
7 an FDA-approved contrast agent dispensed by prescription and accompanied by FDA-approved
8 labeling and package inserts. BDI further admits that any and all contraindications, warnings,
9 precautions, adverse reactions, and/or other information in the MultiHance® labeling and
10 package inserts were approved by the FDA and transmitted to prescribing physicians and/or
11 healthcare providers. BDI fulfilled its obligation under the law to provide adequate warnings
12 and instructions. BDI further denies that gadolinium retention, if any, has been found to cause
13 adverse health effects in patients with normal kidney function, as the FDA again reiterated on
14 December 19, 2017. BDI denies the remaining allegations contained in Paragraph 26 of the
15 Complaint.
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17 27. BDI denies the allegations in Paragraph 27 of the Complaint.

18 28. BDI denies the allegations in Paragraph 28 of the Complaint.

19 29. BDI denies the allegations in Paragraph 29 of the Complaint.

20 30. BDI denies the allegations in Paragraph 30 of the Complaint.

21 31. BDI denies the allegations in Paragraph 31 of the Complaint.

22 32. BDI states that the allegations contained in Paragraph 32 of the Complaint are
23 vague and ambiguous, such that BDI is unable to formulate a response, in that it is not clear
24 what is meant by “the inventors of linear gadolinium-based contrast agents,” and therefore
25 denies the allegations contained in Paragraph 32. To the extent that Paragraph 32 of the
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1 Complaint calls for medical or scientific conclusions prior to discovery, any such response by
2 BDI would be premature at this time, and BDI therefore denies such allegations. BDI further
3 denies that gadolinium retention, if any, has been found to cause adverse health effects in
4 patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

5 33. Paragraph 33 of the Complaint calls for medical or scientific conclusions prior to
6 discovery, such that any response by BDI would be premature at this time, and BDI therefore
7 denies the allegations contained in Paragraph 33 of the Complaint.

8 34. BDI is without sufficient information to form a belief as to the truth, meaning or
9 intent of the allegations contained in Paragraph 34 of the Complaint regarding Magnevist, and
10 therefore denies the same. To the extent that Paragraph 34 of the Complaint calls for medical or
11 scientific conclusions prior to discovery, any such response by BDI would be premature at this
12 time, and BDI therefore denies such allegations.

13 35. Paragraph 35 of the Complaint calls for medical or scientific conclusions prior to
14 discovery, such that any response by BDI would be premature at this time, and BDI therefore
15 denies the allegations contained in Paragraph 35. BDI further denies that gadolinium retention,
16 if any, has been found to cause adverse health effects in patients with normal kidney function,
17 as the FDA again reiterated on December 19, 2017.

18 36. Paragraph 36 of the Complaint calls for medical or scientific conclusions prior to
19 discovery, such that any response by BDI would be premature at this time, and BDI therefore
20 denies the allegations contained in Paragraph 36. BDI further denies that gadolinium retention,
21 if any, has been found to cause adverse health effects in patients with normal kidney function,
22 as the FDA again reiterated on December 19, 2017.

23 37. Paragraph 37 of the Complaint calls for medical or scientific conclusions prior to
24 discovery, such that any response by BDI would be premature at this time, and BDI therefore
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1 denies the allegations contained in Paragraph 37. BDI further denies that gadolinium retention,
2 if any, has been found to cause adverse health effects in patients with normal kidney function,
3 as the FDA again reiterated on December 19, 2017.

4 38. Paragraph 38 of the Complaint calls for medical or scientific conclusions prior to
5 discovery, such that any response by BDI would be premature at this time, and BDI therefore
6 denies the allegations contained in Paragraph 38. BDI further denies that gadolinium retention,
7 if any, has been found to cause adverse health effects in patients with normal kidney function,
8 as the FDA again reiterated on December 19, 2017.

9 39. BDI denies the allegations in Paragraph 39 of the Complaint.

10 40. BDI is without sufficient information to form a belief as to the truth, meaning or
11 intent of the allegations contained in Paragraph 40 of the Complaint regarding Omniscan, and
12 therefore denies the same. To the extent that Paragraph 40 of the Complaint calls for medical or
13 scientific conclusions prior to discovery, any such response by BDI would be premature at this
14 time, and BDI therefore denies such allegations. BDI further denies that gadolinium retention,
15 if any, has been found to cause adverse health effects in patients with normal kidney function,
16 as the FDA again reiterated on December 19, 2017.

17 41. BDI is without sufficient information to form a belief as to the truth, meaning or
18 intent of the allegations contained in Paragraph 41 of the Complaint regarding Magnevist, and
19 therefore denies the same. To the extent that Paragraph 41 of the Complaint calls for medical or
20 scientific conclusions prior to discovery, any such response by BDI would be premature at this
21 time, and BDI therefore denies such allegations. BDI further denies that gadolinium retention,
22 if any, has been found to cause adverse health effects in patients with normal kidney function,
23 as the FDA again reiterated on December 19, 2017.

24 42. BDI denies the allegations in Paragraph 42 of the Complaint.

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1 43. Paragraph 43 of the Complaint calls for medical or scientific conclusions prior to
2 discovery, such that any response by BDI would be premature at this time, and BDI therefore
3 denies the allegations contained in Paragraph 43. BDI further denies that gadolinium retention,
4 if any, has been found to cause adverse health effects in patients with normal kidney function,
5 as the FDA again reiterated on December 19, 2017.

6 44. In response to Paragraph 44 of the Complaint, BDI admits that MultiHance® is
7 an FDA-approved contrast agent dispensed by prescription and accompanied by FDA-approved
8 labeling and package inserts. BDI further admits that any and all contraindications, warnings,
9 precautions, adverse reactions, and/or other information in the MultiHance® labeling and
10 package inserts was approved by the FDA and transmitted to prescribing physicians and/or
11 healthcare providers. BDI fulfilled its obligation under the law to provide adequate warnings
12 and instructions. BDI further denies that gadolinium retention, if any, has been found to cause
13 adverse health effects in patients with normal kidney function, as the FDA again reiterated on
14 December 19, 2017. BDI denies the remaining allegations contained in Paragraph 44 of the
15 Complaint.
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17 45. In response to Paragraph 45 of the Complaint, BDI admits that the FDA warning
18 regarding nephrogenic systemic fibrosis speaks for itself. BDI further admits that MultiHance®
19 is an FDA-approved contrast agent dispensed by prescription and accompanied by FDA-
20 approved labeling and package inserts. BDI further admits that any and all contraindications,
21 warnings, precautions, adverse reactions, and/or other information in the MultiHance® labeling
22 and package inserts were approved by the FDA and transmitted to prescribing physicians and/or
23 healthcare providers. BDI fulfilled its obligation under the law to provide adequate warnings
24 and instructions. To the extent that Paragraph 45 of the Complaint calls for medical or
25 scientific conclusions prior to discovery, any such response by BDI would be premature at this
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PHONE 702.734.7700

1 time, and BDI therefore denies such allegations. BDI further denies that gadolinium retention,
2 if any, has been found to cause adverse health effects in patients with normal kidney function,
3 as the FDA again reiterated on December 19, 2017. BDI denies the remaining allegations
4 contained in Paragraph 45 of the Complaint.

5 46. BDI admits that MultiHance® is an FDA-approved contrast agent dispensed by
6 prescription and accompanied by FDA-approved labeling and package inserts. BDI further
7 admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other
8 information in the MultiHance® labeling and package inserts were approved by the FDA and
9 transmitted to prescribing physicians and/or healthcare providers. BDI denies the remaining
10 allegations in Paragraph 46 of the Complaint.

11 47. BDI states that the allegations contained in Paragraph 47 of the Complaint do not
12 constitute “a short and plain statement” of Plaintiff’s alleged claim, such that BDI is unable to
13 formulate a response. BDI denies that it was ever found liable for causing NSF. BDI admits
14 that MultiHance® is an FDA-approved contrast agents dispensed by prescription and
15 accompanied by FDA-approved labeling and package inserts. BDI further admits that any and
16 all contraindications, warnings, precautions, adverse reactions, and/or other information in the
17 MultiHance® labeling and package inserts was approved by the FDA and transmitted to
18 prescribing physicians and/or healthcare providers. BDI fulfilled its obligation under the law to
19 provide adequate warnings and instructions. BDI further denies that gadolinium retention, if
20 any, has been found to cause adverse health effects in patients with normal kidney function, as
21 the FDA again reiterated on December 19, 2017. BDI denies the remaining allegations
22 contained in Paragraph 47 of the Complaint.

23 48. BDI admits that the medical community does not recognize any disease
24 associated with gadolinium other than NSF. BDI further denies that gadolinium retention, if
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1 any, has been found to cause adverse health effects in patients with normal kidney function, as
2 the FDA again reiterated on December 19, 2017. BDI denies the remaining allegations in
3 Paragraph 48 of the Complaint.

4 49. BDI denies the allegations in Paragraph 49 of the Complaint.

5 50. BDI is without sufficient information to form a belief as to the truth of the
6 allegations in Paragraph 50 of the Complaint, and therefore must deny the same. BDI further
7 denies that gadolinium retention, if any, has been found to cause adverse health effects in
8 patients with normal kidney function, as the FDA again reiterated on December 19, 2017.
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10 51. Paragraph 1 of the Complaint calls for medical or scientific conclusions prior to
11 discovery, such that any response by BDI would be premature at this time, and BDI therefore
12 denies the allegations contained in Paragraph 51. BDI further denies that gadolinium retention,
13 if any, has been found to cause adverse health effects in patients with normal kidney function,
14 as the FDA again reiterated on December 19, 2017.
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16 52. Paragraph 52 of the Complaint calls for medical or scientific conclusions prior to
17 discovery, such that any response by BDI would be premature at this time, and BDI therefore
18 denies the allegations contained in Paragraph 52. BDI further denies that gadolinium retention,
19 if any, has been found to cause adverse health effects in patients with normal kidney function,
20 as the FDA again reiterated on December 19, 2017.

21 53. In response to Paragraph 53 of the Complaint, BDI states that the FDA's public
22 statement speaks for itself. BDI further admits that MultiHance® is an FDA-approved contrast
23 agent dispensed by prescription and accompanied by FDA-approved labeling and package
24 inserts. BDI further admits that any and all contraindications, warnings, precautions, adverse
25 reactions, and/or other information in the MultiHance® labeling and package inserts were
26 approved by the FDA and transmitted to prescribing physicians and/or healthcare providers.
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BDI fulfilled its obligation under the law to provide adequate warnings and instructions. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017. BDI denies the remaining allegations contained in Paragraph 53 of the Complaint.

54. In response to Paragraph 54 of the Complaint, BDI states that the FDA's advisory committee's vote speaks for itself. BDI further admits that MultiHance® is an FDA-approved contrast agent dispensed by prescription and accompanied by FDA-approved labeling and package inserts. BDI further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the MultiHance® labeling and package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. BDI fulfilled its obligation under the law to provide adequate warnings and instructions. BDI denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017. BDI denies the remaining allegations contained in Paragraph 54 of the Complaint.

55. In response to Paragraph 55 of the Complaint, BDI admits the issuance of the May 2018 warning, and states that the document speaks for itself. BDI denies the allegations contained in Paragraph 55 of the Complaint to the extent that they are inconsistent with the content of the May 2018 document. BDI further admits that MultiHance® is an FDA-approved contrast agent dispensed by prescription and accompanied by FDA-approved labeling and package inserts. BDI further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the MultiHance® labeling and package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. BDI fulfilled its obligation under the law to provide adequate warnings and

1 instructions. BDI denies that gadolinium retention, if any, has been found to cause adverse
 2 health effects in patients with normal kidney function, as the FDA again reiterated on
 3 December 19, 2017. BDI denies the remaining allegations contained in Paragraph 55 of the
 4 Complaint, including each and every subpart thereof.

5 56. BDI denies the allegations in Paragraph 56 of the Complaint.

6 **ANSWER TO SECTION ENTITLED**
 7 **"FIRST CAUSE OF ACTION STRICT PRODUCT LIABILITY: FAILURE TO WARN"**

8 57. In response to Paragraph 57 of the Complaint, BDI adopts, realleges and
 9 incorporates herein by reference its answers, affirmative defenses and other matters constituting
 10 an avoidance as set forth in paragraphs 1-56 of this Answer and in its Affirmative and Other
 11 Defenses.

12 58. BDI admits that Plaintiffs have attempted to assert causes of action for personal
 13 injuries and seek to recover damages herein. BDI denies that Plaintiffs are entitled to any
 14 recovery from this defendant, and denies the remaining allegations in Paragraph 58 of the
 15 Complaint.

16 59. BDI admits that Plaintiffs have attempted to assert causes of action for personal
 17 injuries and seek to recover damages herein. BDI denies that Plaintiffs are entitled to any
 18 recovery from this defendant, and denies the remaining allegations in Paragraph 59 of the
 19 Complaint.

20 60. BDI denies the allegations contained in Paragraph 60 of the Complaint.

21 61. BDI denies the allegations contained in Paragraph 61 of the Complaint.

22 62. BDI denies the allegations contained in Paragraph 62 of the Complaint.

23 63. BDI denies the allegations contained in Paragraph 63 of the Complaint.

24 64. BDI denies the allegations contained in Paragraph 64 of the Complaint.

25 WHEREFORE, BDI prays that Plaintiffs take nothing by way of the First Cause of
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1 Action in their Complaint, for judgment in BDI's favor as to Plaintiffs' First Cause of Action, for
 2 BDI's costs and fees incurred herein, and for such further relief deemed just and proper.

3 **ANSWER TO SECTION ENTITLED**
 4 **"SECOND CAUSE OF ACTION NEGLIGENCE"**

5 65. In response to Paragraph 65 of the Complaint, BDI adopts, realleges and
 6 incorporates herein by reference its answers, affirmative defenses and other matters constituting
 7 an avoidance as set forth in paragraphs 1-64 of this Answer and in its Affirmative and Other
 8 Defenses.

9 66. BDI admits that Plaintiffs have attempted to assert causes of action for personal
 10 injuries and seek to recover damages herein. BDI denies that Plaintiffs are entitled to any
 11 recovery from this defendant, and denies the remaining allegations in Paragraph 66 of the
 12 Complaint.

13 67. BDI admits that Plaintiffs have attempted to assert causes of action for personal
 14 injuries and seek to recover damages herein. BDI denies that Plaintiffs are entitled to any
 15 recovery from this defendant, and denies the remaining allegations in Paragraph 67 of the
 16 Complaint.

17 68. To the extent Paragraph 68 of the Complaint states legal conclusions, no
 18 response is required. To the extent BDI may be required to respond, BDI denies that it
 19 breached any duty, and denies the remaining allegations contained in Paragraph 68 of the
 20 Complaint.

21 69. BDI denies the allegations contained in Paragraph 69 of the Complaint.

22 70. BDI denies the allegations contained in Paragraph 70 of the Complaint.

23 71. BDI denies the allegations contained in Paragraph 71 of the Complaint.

24 72. BDI denies the allegations contained in Paragraph 72 of the Complaint.

25 73. BDI denies the allegations contained in Paragraph 73 of the Complaint.

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WHEREFORE, BDI prays that Plaintiffs take nothing by way of the Second Cause of Action in their Complaint, for judgment in BDI's favor as to Plaintiffs' Second Cause of Action, for BDI's costs and fees incurred herein, and for such further relief deemed just and proper.

ANSWER TO SECTION ENTITLED
"PRAYER FOR RELIEF"

BDI denies that Plaintiffs are entitled to any relief as requested in their "Prayer for Relief."

AFFIRMATIVE AND OTHER DEFENSES

By alleging the matters set forth below, BDI does not admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters. If necessary and/or in the alternative, BDI raises the following defenses available in the State of Nevada and any State or Commonwealth of the United States whose laws might be deemed controlling in this case, but reserves the right to amend its Answer to raise any additional defenses which it may have against Plaintiffs' claims:

1. Plaintiffs' claims and causes of action are barred by the applicable statute of limitations, and/or repose, and/or may be otherwise untimely.
2. Plaintiffs fail to state a claim upon which relief can be granted.
3. Plaintiffs fail to plead their claims against BDI with sufficient particularity.
4. MultiHance® is a contrast imaging agent which is available only upon prescription of a licensed physician. Any warnings that BDI gave were transmitted to prescribing physicians and/or healthcare providers. Under applicable state law, BDI fulfilled its obligation to provide adequate warnings and instructions. Plaintiffs' claims are therefore barred pursuant to the learned intermediary doctrine.
5. If Plaintiffs sustained the injuries or damages as alleged, said injuries and expenses were directly and proximately caused by the acts and omissions (wrongful or

1 otherwise), negligence, sole fault, misuse, abuse, modification, alteration, omission, or fault of
2 one or more parties other than BDI over whom BDI had no supervision or control and for whose
3 actions and omissions BDI has no legal responsibility. BDI is not liable for negligence and
4 violated no duty that may have been owed to Plaintiffs.

5 6. BDI's activities conformed to all state and federal statutes, regulations, and
6 industry standards based upon the state of the knowledge that existed at the time.

7 7. Plaintiffs' recovery is barred and/or should be reduced under the applicable law
8 because of Plaintiffs' contributory negligence or fault, comparative negligence or fault, culpable
9 conduct, intentional acts, assumption of risk, and/or want of care.

10 8. Plaintiffs' injuries and damages, if any, resulted from an intervening or
11 superseding cause or causes and any act or omission on the part of BDI was not the proximate
12 and/or competent producing cause of such alleged injuries or damages.

13 9. Plaintiffs' Complaint fails to state a claim upon which relief can be granted in that
14 the methods, standards and techniques utilized with respect to the design, manufacture,
15 marketing, distribution, and sale of MultiHance®, including adequate warnings and instructions
16 with respect to the product's use included in the product's package insert and other literature,
17 conformed to the applicable state of the art. The product in question, including its FDA-
18 approved labeling, complied with the state of scientific and medical knowledge available to BDI
19 at the time of its manufacture, distribution, and sale.

20 10. With respect to each and every purported cause of action, the acts of BDI were at
21 all times done in good faith and without malice.

22 11. Plaintiffs' claims are barred in whole or in part under comment k to Section 402A
23 of the Restatement (Second) of Torts.

12. Plaintiffs' claims are barred in whole or in part because BDI provided legally adequate "directions or warnings" as to the use of the product at issue within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

13. Plaintiffs' claims are barred as a matter of law pursuant to Sections 2, 4, 6(c), 6(d) and comment f to Section 6, of the Restatement (Third) of Torts: Products Liability.

14. With respect to each and every cause of action, Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegate Plaintiffs' claims to a negligence cause of action.

15. MultiHance® complied with all applicable state and federal statutes regarding the product in question, including product safety regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations as well as the industry standards based upon the state of knowledge existing at the relevant time alleged in by the Complaint. The product at issue was reasonably fit, suitable, and safe for its intended uses, demonstrating that due care was exercised with respect to the design, manufacture, testing, marketing, distribution, and sale of MultiHance®. In the event that Plaintiffs' claims are not barred, BDI is entitled to a presumption that the product in question is free from any defect or defective condition as the plans or design for the product or the methods and techniques of manufacturing, inspecting, and testing the product were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the product or the methods and techniques of manufacturing, inspecting, and testing the product were adopted.

16. Plaintiffs' claims are barred because MultiHance® was neither defective nor unreasonably dangerous in its design, manufacture, distribution, or marketing, and was reasonably safe and reasonably fit for its intended uses, thereby barring Plaintiffs' recovery.

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PHONE: 702.470.0000

1 17. If Plaintiffs sustained the injuries or damages as alleged, said injuries or damages
2 were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of
3 MultiHance®, thereby barring Plaintiffs' recovery against BDI.

4 18. Plaintiffs' claims are barred to the extent Plaintiffs knew the condition of
5 MultiHance®, appreciated the risks of injury flowing from use of the product, and nevertheless
6 proceeded to use the product without regard to the danger of such risks. As a result, Plaintiffs
7 gave informed consent and/or assumed the risk of injury of which they now complain.

8 19. Plaintiffs' claims are barred to the extent Plaintiffs' prescribing health care
9 provider knew the condition of MultiHance®, appreciated the risks of injury flowing from use of
10 the product, and nevertheless proceeded to use the product in the exercise of the prescribing
11 health care provider's medical judgment.

12 20. The extent of any risk associated with the use of the product at issue, the existence
13 of which is not admitted, was, at the time of the distribution of said products by BDI, unknown
14 and could not have been known by the use of ordinary care.

15 21. The public interest in the benefit and availability of the products which are the
16 subject matter of this action precludes liability, if any, resulting from any activities undertaken
17 by BDI, which were unavoidable given the state of human knowledge at the time those activities
18 were undertaken. With respect to Plaintiffs' claims, if it is determined there exists a risk inherent
19 in the subject products, then such risk, if any, is outweighed by the benefits of the products.

20 22. Plaintiffs' failure to warn claim is barred given that BDI had no duty to warn of
21 risks of which it neither knew nor should have known at the time the products were designed,
22 distributed, and manufactured.

23 23. Plaintiffs' injuries and damages, if any, were the result of an idiosyncratic
24 reaction that BDI could not have reasonably foreseen, thereby barring Plaintiffs' recovery.
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(702) 201-7000

24. Plaintiffs' claims are barred because the alleged injuries and damages, if any, were caused by medical conditions, disease, illness, or processes (whether pre-existing or contemporaneous) unrelated to any conduct of BDI or condition of MultiHance®, thereby barring Plaintiffs' recovery.

25. Plaintiffs have not sustained an ascertainable loss of property or money, nor any actual injury or damages.

26. Plaintiffs' claims are barred under the doctrine of economic loss.

27. Plaintiffs failed to mitigate their alleged damages.

28. BDI's advertisements and labeling with respect to the products which are the subject of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution and this State.

29. BDI is entitled to protection under the *Noerr-Pennington* doctrine, which provides that parties who exercise their First Amendment right to communicate and/or petition the government are immune from liability premised on any such efforts.

30. BDI denies any liability, but if BDI is ultimately found liable to Plaintiffs, then it should only be liable for its equitable share of Plaintiffs' recovery since any liability which would be found against BDI will be insufficient to impose joint liability.

31. If Plaintiffs recover from BDI, BDI is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause the Plaintiffs' alleged damages.

32. Any verdict or judgment rendered against BDI must be reduced by those amounts that have, or will, with reasonable certainty, replace or indemnify Plaintiffs in whole or in part,

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1 for any past or future claimed economic loss from any collateral source, such as insurance, social
2 security, worker's compensation, or employee benefit programs.

3 33. Plaintiffs' damages, if any, are barred or reduced by the doctrine of avoidable
4 consequences.

5 34. To the extent Plaintiffs have settled or will in the future settle with any person or
6 entity with respect to the injuries asserted in the Complaint, BDI's liability, if any, should be
7 precluded or reduced accordingly.

8 35. To the extent Plaintiffs seek recovery of punitive or exemplary damages against
9 BDI, unless BDI's liability for punitive damages and the appropriate amount of punitive
10 damages is required to be established by clear and convincing evidence, any award of punitive
11 damages would violate BDI's constitutional rights, including but not limited to those under the
12 due process clauses in the Fifth and Fourteenth Amendments to the United States Constitution
13 and any applicable state constitution, and would be improper under the common law, public
14 policies, applicable statutes and court rules of the applicable states to these amendments and the
15 excessive fines clause in the Eighth Amendment to the Constitution of the United States and
16 double jeopardy clause in the Fifth Amendment to the Constitution of the United States.

17 36. To the extent Plaintiffs seek recovery of punitive or exemplary damages against
18 BDI, any such claim of Plaintiffs for punitive damages against BDI cannot be maintained
19 because there was no act or omission by BDI that was oppressive, fraudulent, or malicious.
20 Additionally, any award of punitive damages under the applicable law would be unlawful and
21 unauthorized, and would be void for vagueness, both facially and as applied, as a result of,
22 among other deficiencies, the absence of adequate notice of what conduct is subject to
23 punishment; the absence of adequate notice of what punishment may be imposed; and the
24 absence of a predetermined limit, such as a maximum multiple of compensatory damages or a
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1 maximum amount of punitive damages that a jury may impose, all in violation of the due process
2 clause of the Fourteenth Amendment to the United States Constitution, the applicable state
3 constitution, and the common law and public policies of that state.

4 37. To the extent Plaintiffs seek recovery of punitive damages against BDI, any such
5 claim of Plaintiffs for punitive damages against BDI cannot be maintained because any award of
6 punitive damages under the applicable law would be by a jury that (1) is not provided standards
7 of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive
8 damages award, (2) is not adequately instructed on the limits of punitive damages imposed by
9 the applicable principles of deterrence and punishment, (3) is not expressly prohibited from
10 awarding punitive damages, or determining the amount of an award of punitive damages, in
11 whole or in part, on the basis of invidiously discriminatory characteristics, including residence,
12 wealth, and corporate status of BDI, (4) is permitted to award punitive damages under a standard
13 for determining liability for punitive damages that is vague and arbitrary and does not define
14 with sufficient clarity the conduct or mental state that makes punitive damages permissible, (5) is
15 permitted to award punitive damages based on out-of-state conduct, conduct that complied with
16 applicable law, or conduct that was not directed, or did not proximately cause harm, if any, to
17 Plaintiff, (6) is permitted to award punitive damages in an amount that is not both reasonable and
18 proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory
19 damages, if any, (7) is not subject to adequate, independent, de novo trial court and appellate
20 judicial review for reasonableness and furtherance of legitimate purposes on the basis of
21 objective standards and in conformity with the United States Constitution as amended or any
22 applicable State constitution. Any such verdict would violate BDI's due process rights
23 guaranteed by the Fourteenth Amendment to the United States Constitution and by the due
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process and equal protection provisions of any applicable state constitution, and would be improper under the common law and public policies of that state.

38. Additionally, punitive damages may not be recovered to the extent such damages are: (1) imposed where state law is impermissibly vague, imprecise, or inconsistent, (2) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, or (3) imposed on the basis of anything other than BDI's conduct within the State where Plaintiffs reside, or in any other way subjecting BDI to impermissible multiple punishment for the same alleged wrong.

39. To the extent Plaintiffs seek recovery of punitive or exemplary damages against BDI, any award of punitive damages based on anything other than BDI's conduct in connection with the design, manufacture, and sale of MultiHance® would violate the due process clause of the Fourteenth Amendment of the United States Constitution and the due process provisions of the applicable state constitution, and would be improper under the common law and public policies of that state, because any other judgment for punitive damages in this case cannot protect BDI against impermissible punishment for the same wrong and against punishment for extraterritorial conduct, including conduct that is lawful in states other than the applicable state. In addition, any award would violate principles of comity under the laws of that state.

40. BDI incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts under the Due Process Clause of the Fourteenth Amendment to the United States Constitution, including but not limited to standards set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny.

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LAS VEGAS, NV 89149

(702) 204-7000

1 41. BDI asserts the provisions of all applicable statutory caps on damages of any sort,
2 including compensatory, punitive, non-economic or exemplary damages, under applicable
3 regulations and/or laws.

4 42. There was no practical or technically feasible alternative design or formulation
5 that would have prevented the harm alleged by Plaintiffs or reduced the alleged risk, without
6 substantially impairing the usefulness, safety, efficacy, or intended purpose of MultiHance®,
7 thereby barring Plaintiffs' recovery.

8 43. To the extent Plaintiffs' claims are based on alleged misrepresentations or
9 omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal*
10 *Committee*, 531 U.S. 341 (2001).

11 44. The BDI products at issue have been formulated, designed, tested, manufactured,
12 processed, distributed, and labeled in accordance with the provisions of the Federal Food, Drug
13 and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and regulations promulgated thereunder. Therefore,
14 Plaintiffs' claims predicated on state tort law and alleging that MultiHance® is unsafe are barred,
15 in whole or in part, by the doctrine of federal preemption and the Supremacy Clause of the
16 United States Constitution, Article IV, clause 2.

17 45. To the extent that Plaintiffs assert claims based on BDI's adherence to and
18 compliance with applicable state laws, regulations, and rules, such claims are preempted by
19 federal law under the Final Rule, Requirements on Content and Format of Labeling for Human
20 Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

21 46. Plaintiffs' claims are barred and/or this Court should defer this matter, in whole or
22 in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with
23 regulating drugs, including the products at issue, and is specifically charged with determining the
24 content of warnings and labeling for drugs.

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LAS VEGAS, NV 89149
(702) 204-7600

1 47. Plaintiffs' claims may be barred by failure to join an indispensable party or real
2 party in interest necessary for the just adjudication of this matter.

3 48. BDI is entitled to the protections and limitations afforded under the law of
4 Plaintiffs' state of residence and any other state whose law is deemed to apply in this case.

5 49. To the extent Plaintiffs' claims are based on a theory providing for liability
6 without proof of causation, the claims violate BDI's rights under the United States Constitution.

7 50. Plaintiffs received all or substantially all of the benefit from the subject product
8 that Plaintiffs hoped and intended to receive, and to that extent, any damages and/or restitution
9 that Plaintiffs might be entitled to recover from BDI must be correspondingly barred or reduced.
10

11 51. Plaintiffs' claims are barred by laches, waiver, accord and satisfaction, payment,
12 release, res judicata, estoppel, spoliation of evidence, and/or the applicability of arbitration and
13 award.

14 52. This case may be subject to dismissal or stay on the grounds of *forum non*
15 *conveniens*.
16

17 53. Plaintiffs are not entitled to recover attorneys' fees under any applicable law.

18 54. The Complaint fails to give BDI reasonable notice of facts sufficient to complete
19 a choice of law analysis. Pending a determination of applicable law, BDI has pleaded applicable
20 affirmative defenses under Nevada law, and reserves the right to assert further or additional
21 affirmative defenses if it is determined that such defenses exist under the law of the state(s) in
22 which Plaintiffs reside or were allegedly first injured.
23

24 55. BDI adopts, by reference, each and every defense asserted by any other defendant
25 in this matter that are applicable to BDI.

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PRAYER

WHEREFORE, Defendant Bracco Diagnostics, Inc. prays that:

1. Plaintiffs take nothing by reason of their Complaint;
2. The Complaint against this defendant be dismissed in its entirety;
3. Defendant recover its costs; and
4. This Court award such other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Defendant Bracco Diagnostics, Inc. demands trial by jury on all claims so triable.

Dated this 19th day of September, 2018.

ALVERSON TAYLOR & SANDERS

By



LEANN SANDERS, ESQ.

Nevada Bar No.: 000390

JOEL BROWNING, ESQ.

Nevada Bar No.: 014489

6605 Grand Montecito Parkway, Ste. 200

Las Vegas, NV 89149

(702) 384-7000

efile@alversontaylor.com

Thomas N. Sterchi (*Pro Hac Vice* motion to be filed)

Paul S. Penticuff (*Pro Hac Vice* motion to be filed)

BAKER STERCHI COWDEN & RICE, L.L.C.

2400 Pershing Road, Suite 500

Kansas City, MO 64108

Telephone: (816) 471-2121

sterchi@bscr-law.com

penticuff@bscr-law.com

Attorneys for Defendant

BRACCO DIAGNOSTICS, INC.

ALVERSON TAYLOR & SANDERS

LAWYERS

6605 GRAND MONTECITO PKWY STE 200

LAS VEGAS, NV 89149

(702) 384-7000

CERTIFICATE OF SERVICE

Pursuant to FRCP 5, I hereby certify that I am an employee of ALVERSON, TAYLOR, & SANDERS and that on the 19th day of September, 2018, I caused to be served via CM/ECF a true and correct copy of **DEFENDANT, BRACCO DIAGNOSTIC, INC.'S ANSWER TO PLAINTIFFS' COMPLAINT.**

Robert J. Drakulich, Esq.
Nicholas J. Drakulich, Esq.
THE DRAKULICH FIRM, APLC
245 E. Liberty Street, Ste. 510
Reno, NV 89501

Todd A. Walburg (Pro Hac Vice Pending)
CUTTER LAW, P.C.
401 Watt Avenue
Sacramento, CA 95864

Attorneys for Plaintiffs


An Employee of
ALVERSON TAYLOR & SANDERS

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ALVERSON TAYLOR & SANDERS

LAWYERS

6605 GRAND MONTECITO PKWY STE 200

LAS VEGAS, NV 89149

702.731.2047